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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,265	03/27/2002	Rajen Shah	4-31158A	2975
1095	7590	07/14/2004	EXAMINER	
NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 430/2 EAST HANOVER, NJ 07936-1080			JOYNES, ROBERT M	
			ART UNIT	PAPER NUMBER
			1615	
DATE MAILED: 07/14/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,265	SHAH ET AL.	
	Examiner Robert M. Joynes	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on April 19, 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2-5 and 8 is/are pending in the application.
- 4a) Of the above claim(s) 1,6 and 7 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 2-5 and 8 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>April 19, 2004</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Receipt is acknowledged of applicants' Response and Information Disclosure

Statement filed on April 19, 2004.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyamoto et al. (US 5962535) in combination with Faour et al. (US 6004582).

Miyamoto teaches compositions for treating Alzheimer's disease wherein the compositions comprise idebenone in combination with an acetylcholinesterase inhibitor such as rivastigmine (Col. 2, lines 50-67; Col. 3, lines 1-65; Col. 9, lines 36-67; Col. 10, lines 1-2). The compositions are in the form of tablets, capsules and granules (Col. 10, lines 52-58). The tablets, capsules and granules can be coated for sustained release purposes and are manufactured by the known technology in the art (Col. 11, lines 5-10).

Miyamoto does not expressly teach the exact formulation of the tablets, capsules and granules.

Faour teaches a multi-layer composition comprising a core with an active agent; a semi-permeable membrane; a water-soluble coating; and an external coat that also contains an active for immediate release (Col. 3, line 49 – Col. 4, line 18). The compositions are suitable for a variety of drugs and pharmaceuticals, including antipsychotics and neuroleptics (Col. 13, lines 38-67). The device can be formulated to deliver the actives in a controlled manner in a variety if release mechanisms (Col. 5, lines 58-64).

Miyamoto and Faour do not expressly teach a coating thickness or an exact time for release of the drug from the composition once administered.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a composition comprising rivastigmine and containing multiple layers for controlling the release of the active agent. Miyamoto teaches that rivastigmine can be formulated into tablets, capsules, and/or granules by techniques known in the art. Faour teaches one such techniques that is known in the art that comprises a core with an active and multiple layers of coatings to control the release of the active.

One of ordinary skill in the art would have been motivated to do this deliver the active agent over an extended period of time to most effectively deliver the active agent. One would be motivated further to use such a composition to control the location of delivery of the active, i.e., deliver the drugs in the stomach or the colon.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed April 19, 2004 have been fully considered but they are not persuasive. Applicants argue that no motivation to combine the references exists.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Miyamoto reference teaches a combination of idebenone and an acetylcholinesterase inhibitor, wherein rivastigmine is the preferred compound. This reference further teaches that a sustained release formulation can be made by techniques known in the art. The Faour reference teaches one such known sustained release formulation that can be implemented for a variety of drugs. In other words, the Miyamoto reference teaches a combination of drugs and suggests to use techniques known in the art to sustain the release of the drugs. Faour teaches a known sustained release formulation that can be used not only with the types of drugs recited in the Miyamoto reference but has a wide application for a variety of drugs. Faour teaches that the site of release can be

controlled and varied depending upon the drug to be incorporated or the site to be targeted. It is a known technique for sustaining the release of drugs.

Further, it is the position of the examiner that the coating thickness and release times are limitations that would be routinely determined by one of ordinary skill in the art, through minimal experimentation, as being suitable, absent the presentation of some unusual and/ or unexpected results. The results must be those that accrue from the specific limitations.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1615

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (571) 272-0597. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert M. Joynes
Patent Examiner
Art Unit 1615


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